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PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Darren A. Janzig; Carl D. Wahlstrand; Robert M. Skime; Mark S. Lent; Keith A. Miesel; James E. Cabak

Confirmation No. 3259

Serial No.: 10/731,699

Filed: December 9, 2003 Customer No.: 28863

Examiner: George C. Manuel

Group Art Unit: 3762

Docket No.: 1023-331US01

Title: COUPLING MODULE OF A MODULAR IMPLANTABLE MEDICAL DEVICE

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REPLY BRIEF

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a Reply Brief responsive to the Examiner's Answer mailed July 16, 2008, the Office Action mailed October 25, 2007 and the Advisory Action dated February 14, 2008. The due date for this Reply Brief is September 16, 2008.

No fees are believed to be due at this time. Please charge any fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

Appeal Brief for Application Number 10/731,699
Reply to Examiner's Answer mailed July 16, 2008

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STATUS OF CLAIMS

Claims 1, 3-11, 13-15 and 17-25 are on appeal in this case.

Claims 7-11, 14, 15, 17 and 20-23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hirschberg et al. (US 5,312,440, hereinafter "Hirschberg").

Claim 25 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Lynch (US 4,934,368).

Claims 1, 3-6 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lynch.

Claims 7, 8, 19 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meltzer (US 5,645,586).

Claims 12, 13, 18 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hirschberg.

Claim 1 also stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending US Pat. No. 7,212,864.

Claims 2, 12 and 16 are currently canceled and are not on appeal.

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GROUND S OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following grounds of rejection to be reviewed on Appeal:

- (1) The first ground of rejection to be reviewed is the rejection of claim 25 under 35 U.S.C. § 102(b) as being anticipated by Lynch (US 4,934,368).
- (2) The second ground of rejection to be reviewed is the rejection of claims 7-11, 14, 15, 17 and 20-23 under 35 U.S.C. § 102(b) as being anticipated by Hirschberg et al. (US 5,312,440, hereinafter "Hirschberg").
- (3) The third ground of rejection to be reviewed is the rejection of claims 12, 13, 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Hirschberg.
- (4) The fourth ground of rejection to be reviewed is the rejection of claims 1, 3-6 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Lynch.
- (5) The fifth ground of rejection to be reviewed is the rejection of claims 7, 8, 19 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer (US 5,645,586).
- (6) The sixth ground of rejection to be reviewed is the rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending US Pat. No. 7,212,864.

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ARGUMENT

In the Examiner's Answer to Appellant's Appeal Brief, the Examiner provided some new arguments in the section titled, "Response to Argument" beginning on page 5 of the Examiner's Answer. For brevity, this Reply Brief addresses these arguments only. Accordingly, this Reply Brief is not intended to address all arguments provided in the Examiner's Answer, and Appellant requests full consideration of all arguments as set forth in the Appeal Brief.

FIRST GROUND OF REJECTION UNDER APPEAL

GROUP 1 - (Claim 25)

Claim 25 is rejected under 35 U.S.C. § 102(b) as being anticipated by Lynch (US 4,934,368). The rejection relies upon the characterization that lead 3 is inherently hermetically sealed to both implant case 12 and nerve cuff 2 using silicon rubber.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."¹ "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."² In this instance, Lynch fails to expressly or inherently describe the limitation of wherein the coupling module is hermetically fixed to the first and second housings as recited in claim 25.

The Examiner's Answer failed to support the contention that lead 3 is inherently hermetically sealed to both implant case 12 and nerve cuff 2 using silicone rubber. Lynch actually teaches away from the concept that implant case 12 and nerve cuff 2 are each hermetically sealed to lead 3. Lynch discloses that master circuitry case 8 is hermetically sealed to protect master circuit 6 from contamination.³ Lynch further discloses that hermitically sealed master circuitry case 8 is enclosed in implant case 12 and that implant case 12 provides "positive environmental protection" for the termination of the leads 3 into master circuitry case 8 via outer seal 13 and inner seal 14.⁴ In this manner, Lynch discloses master circuitry case 8 is hermetically

¹ *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

² *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

³ Lynch, column 6, lines 20-21.

⁴ Lynch, column 6, lines 40-47.

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sealed, but states that implant case 12 provides positive environmental protection. The use of these two terms suggests that positive environmental protection is a level of sealing that is different than hermetic sealing. If implant case 12 were hermetically sealed, logically, Lynch would have stated as much. For this reason, lead 3 is not inherently hermetically sealed to both implant case 12 and nerve cuff 2.

Applicant does not argue that one would not have considered it obvious to utilize double walled sealing according to Lynch's teachings as stated in the Examiner's Answer.⁵ Rather Appellant argues one would not have considered it obvious to modify Lynch to provide a hermetic seal between lead 3 and implant case 12 as well as between lead 3 and nerve cuff 2. Even if Lynch discloses double wall sealing is desirable, that does not mean that double wall hermetic sealing is desirable.

The Examiner has failed to meet the burden of establishing a prima facie case of anticipation with respect to independent claim 25. Reversal of this rejection is requested.

SECOND GROUND OF REJECTION UNDER APPEAL

The Office Action rejected claims 7-11, 14, 15, 17 and 20-23 under 35 U.S.C. § 102(b) as being anticipated by Hirschberg et al. (US 5,312,440, hereinafter "Hirschberg").

GROUP 2 - (Claims 7, 8, 11 and 20-23)

With respect to independent claim 7, Hirschberg fails to teach or suggest a coupling module that is made of a metal that defines at least one lumen. In the rejection of claim 7, the Office Action cited lead 9 of Hirschberg as being equivalent to the coupling module recited in claim 7. However, in contrast to the coupling module recited in claim 7, lead 9 is not made of a metal that defines at least one lumen. Nothing in Hirschberg remotely suggests that lead 9 is made of metal that defines a lumen. Assuming, for the sake of argument, that lead 9 includes metal, e.g., a conductor, such metal does not define a lumen, as required by independent claim 7.

In response to this argument, the Examiner's Answer states that lead 9 of Hirschberg is a wire with insulation.⁶ Applicant agrees with this characterization of lead 9 of Hirschberg.

⁵ Examiner's Answer, page 6.

⁶ Examiner's Answer, page 7.

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Nonetheless, a lead consisting of a metal wire surrounded by insulation is not a coupling module that is made of a metal that defines at least one lumen. To the extent that lead 9 may be considered to include a lumen, that lumen is defined by the insulator, not by the wire conductor.

The characterization that a wire conductor defines a lumen simply because it is surrounded by an insulator is an unreasonably broad construction of the limitation of "wherein the coupling module is made of a metal that defines at least one lumen between the first and second housings" in Appellant's claim 7. The words of a claim are generally given their ordinary and customary meaning, which is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective date of the patent application.⁷ The person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the term appears, but in the context of the entire patent, including the specification and prosecution history.⁸

In this instance, Applicant's specification does not include any suggestion that a wire or other solid element may be used to define a lumen. Instead, Applicant's specification makes clear that a coupling module defining a lumen is a coupling module with a hollow passageway.⁹ In this context, the wire of lead 9 disclosed by Hirschberg can not reasonably be considered to define a lumen as recited in claim 7.

At least because the rejection of claim 7 relies on the Examiner's characterization of lead 9 as a coupling module that is made of a metal that defines at least one lumen as recited in claim 7, the Examiner has failed to meet the burden of establishing a prima facie case of obviousness with respect to independent claim 7 and dependent claims 8, 11 and 20-23. Reversal of this rejection is requested.

GROUP 7 - (Claim 17)

Claim 17 specifies that the metal of claim 7 comprises titanium; claim 7 states that the coupling module is made of a metal that defines at least one lumen. The rejection of claim 7 relies on the characterization that lead 9 is the coupling module of claim 7. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or

⁷ *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citations omitted).

⁸ *Phillips*, 415 F.3d at 1313.

⁹ See, e.g., Applicant's specification as filed, paragraph [0061].

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inherently described, in a single prior art reference."¹⁰ To support the rejection of claim 17, Hirschberg must disclose that lead 9 comprises titanium. Hirschberg does not disclose such a feature. For this reason the rejection of claim 17 should be reversed.

The Examiner's Answer states that the housings of Hirschberg comprise lumens that receive lead 9, which is characterized as the coupling module of Applicant's claim 7.¹¹ However, the composition of the housings is irrelevant to the subject matter of claim 17.

Hirschberg fails to teach or suggest each and every element of independent claim 7 as well as elements recited in claim 17. For at least these reasons, the rejection of claim 17 is improper and should be reversed.

GROUP 3 - (Claim 9)

Dependent claim 9 is patentable for at least the reasons independent claim 7 is patentable. In addition, dependent claim 9 recites that the coupling module defines at least two lumens. Hirschberg fails to teach or suggest a coupling module defining at least two lumens. For example, Hirschberg does not disclose that lead 9 includes at least two lumens.

In response to this argument, the Examiner's Answer states that lead 9 of Hirschberg "has two ends with a lumen at each end sharing the same axis making the lumens co-axial lumens."¹² Applicant respectfully disagrees. Lead 9 does not include two lumens. Lead 9 of Hirschberg clearly includes, at most, a single lumen defined by the insulator. The Examiner's interpretation of different ends of a single lumen to be two different co-axial lumens is clearly unreasonable, and for at least this reason the rejection of claim 9 must be reversed.

Furthermore, as discussed previously in this paper, the rejection of claim 7 characterized lead 9 as an insulator over a wire conductor. While such a configuration may be considered to provide a lumen defined by the insulator, it does not define lumens as recited in claim 9, but instead defines only one lumen.

At least because the rejection of claim 9 relies on the Examiner's characterization of lead 9 as a coupling module that defines at least two lumens, the Examiner has failed to meet the burden of establishing a prima facie case of obviousness. Reversal of this rejection is requested.

¹⁰ *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

¹¹ Examiner's Answer, page 8.

¹² Examiner's Answer, page 7.

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THIRD GROUND OF REJECTION UNDER APPEAL

GROUP 8 - (Claim 13)

Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hirschberg. The Examiner's answer argues that a bellows section would be useful to permit axial flexibility.¹³ However, this argument is insufficient to support the conclusion of obviousness. For example, lead 9 is presumably flexible without a bellows section such that it is unclear how lead including a bellows section would add any functionality over lead 9. In addition, it is not even apparent how lead 9 could include a bellows section as lead 9 does not include a hollow cavity. As another example, the Examiner has failed to cite any prior art reference disclosing a bellows section.

Hirschberg fails to teach or suggest each of the features of claim 13 and independent claim 7, and the Examiner has failed to establish a prima facie case of obviousness with respect claim 13. The rejection of claim 13 is improper and should be reversed.

FOURTH GROUND OF REJECTION UNDER APPEAL

GROUP 11 - (Claims 1, 3, 5 and 24)

The Office Action rejected claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Lynch. The Examiner's Answer questions Applicant's assertion in the Appeal Brief that a dip coating on each of cuff 2, lead 3 and case 12 may not absorb lateral strain on leads 3 in the same way as a separate layer of silicone 25 at only where lead 3 enters case 12.

The modification cover all of lead 3 with a dip coating as proposed by the Examiner would limit the flexibility of lead 3 throughout its length, which would be undesirable. For example, because of the limited flexibility of lead 3 throughout its length, the interface of lead 3 and case 12 would not have a higher stiffness than the read of lead 3 in order to absorb lateral strain. The Examiner's Answer concluded that, "it would appear the dip coating would provide a more uniform coating so that strains in the coating would necessarily be more evenly distributed."¹⁴ However, one of ordinary skill in the art would understand that strain on the

¹³ Examiner's Answer, page 8.

¹⁴ Examiner's Answer, page 8.

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coating is not important, but strain on the conductors would be important. Because the interface between lead 3 and case 12 is a location where lead 3 is predisposed to bending sharply, the interface between lead 3 and case 12 is an area which might have a high stress on the conductors within lead 3. This is the most likely reason Lynch discloses that layer of silicone 25 where lead 3 enters case 12 may be useful to limit lateral strain. Coating all of lead 3 would not produce a similar result of limiting bending specifically where lead 3 enters case 12. In this manner, the modification proposed by the Examiner would appear to defeat the stated advantage of absorbing lateral strain using a layer of silicone 25 where lead 3 enters case 12. For this reason, one of skill in the art would find the modification of a dip coating covering lead 3 to be undesirable.

Lynch fails to teach or suggest Appellant's invention as recited in claim 1. For at least these reasons, the rejection of claim 1 is improper and should be reversed.

CONCLUSION


The Examiner has failed to meet the burden of establishing a prima facie case of anticipation or obviousness with respect to claims 1, 3-11, 13-15 and 17-25 for the reasons addressed above as well as the reasons set out in the Appeal Brief. The final rejection of claims 1, 3-11, 13-15 and 17-25 is improper and should be reversed, and all of the pending claims should be allowed.

Respectfully submitted,

Date: September 16, 2008

By:

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